Title: An appraisal of the use of the Kramer's scale in predicting hyperbilirubinaemia in healthy full term infants.

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ABSTRACT

Objective: Although jaundice is a common condition of the newborn, it rarely reaches levels that require intervention. Despite this, frequent assessments of serum bilirubin levels are made causing unnecessary trauma to the infant and family and avoidable costs to the facility. The objective of the present study was to assess whether cephalocaudal progression of jaundice (measured by Kramer's scale) could be useful as measure to detect which infants in a well baby nursery require testing.

Methods: Four hundred and five infants admitted to postnatal wards at a large teaching Hospital in Brisbane were assessed for jaundice using Kramer's scale. Levels of jaundice were compared using the total serum bilirubin level as the reference standard. The scale was assessed using sensitivity, specificity, positive and negative predictive values.

Results: There was a low level of agreement between jaundice predicted by Kramer's scale and the reference standard. At $\leq$ 48 hours the sensitivity was 67% and specificity was 48%. The positive and negative predictive values were 4% and 98% respectively. Between 49 and 72 hours the sensitivity was 89% and specificity was 54% with a positive predictive value 10% and a negative predictive value 99%. Of the 111 infants who had blood drawn for testing, who were over 72 hours of age, none required phototherapy.

Conclusion: Using Kramer's scale to assess which infants require intervention for jaundice leads to over servicing. If the number of unnecessary tests is to be reduced, more accurate methods for identifying infants who may be at risk for hyperbilirubinaemia must be used.

INTRODUCTION

Neonatal jaundice affects approximately 60 percent of full-term infants and almost every premature infant.[1] For the vast majority of these newborns increased total serum bilirubin (TSB) levels are benign and transitory[2] with only 5% reaching levels that require treatment.[3] Extreme hyperbilirubinaemia is a relatively rare occurrence with 0.42 percent of infants who undergo testing having TSB levels above 342 μmol/L.[4-5] Despite this, between 17 - 52% of infants have blood taken for bilirubin testing.[5] Jaundice meters have been developed and refined to more effectively target those who may require treatment [6-9] and, although they seem to be cost effective[10] their use is not widespread.

The decision for laboratory testing rests with those caring for the infant, generally the midwife, and is generally based on clinical observation. This is certainly the case in our hospital but we have no policy for ordering such tests. In 1998, a six-month review of our request patterns indicated that approximately 78% of TSB level tests were ordered unnecessarily. That is, results did not reach levels at which phototherapy should 'be considered' or 'be required' as defined by the American Academy of Pediatrics guidelines.[11] These guidelines assess the need for interventions (such as phototherapy or transfusion) by considering the TSB level in relation to the infant's age. The guideline is a widely used reference or 'gold standard' when making decisions about interventions for neonatal jaundice.

One simple approach that has been used elsewhere to determine the need for serum bilirubin testing is the progression of yellow discolouration of the skin from the head to the feet or cephalocaudal progression using the Kramer's scale[12]. The scale is based on a 1969 study of 108 full term infants which found that bilirubin concentrations were correlated to 5 specific 'dermal zones' (i) head and neck, (ii) upper trunk, (iii) lower trunk and thighs, (iv) arms and legs below the knees, (v) hands and feet. Lowest TSB levels were associated with yellow discoloration of the head and neck only and highest levels where the discolouration extended to the hands and feet.

The primary aim of this study was to assess if the Kramer's scale could be used as a screening instrument to determine which infants require TSB level testing in a well baby nursery.

METHODS

Sample:

The study was conducted at a large metropolitan teaching hospital in Brisbane, Australia where approximately 5,000 infants are born each year. A convenience sample of otherwise healthy infants who were 38 weeks or over, for whom a request for a TSB level was made, were included in the study. Neonates who were admitted to the neonatal intensive care unit or special care unit were excluded.

Procedure:

Before commencing the investigation midwives on the postnatal wards received education about the study including the use of the Kramer's scale, a visual assessment tool to identify levels of jaundice (see Fig 1). When a TSB level test was ordered, information including demographic details, method of delivery and infant feeding method was collected. To assess the level of jaundice the infant's skin was blanched using thumb pressure and the colour of the underlying skin noted. Observations were taken under florescent lighting augmented by natural lighting during daylight hours or under florescent lighting alone depending on when the test was ordered. While this meant that visual assessments of the infants were made under varying circumstances it reflects the reality of clinical practice. A trained phlebotomist took all blood tests. Results of the bilirubin test were obtained from the Hospital's on-line result service. Ethics approval for the study was not required as there were no intervention outside normal care.

Statistical analysis:

Statistical analysis was carried out using SPSS for Windows, version 12.01 (SPSS Inc. Chicago 2003). Standard descriptive statistics were calculated for all variables. Differences between proportions were compared using the χ^2 test with Yate's correction or two-tailed Fisher's exact test if appropriate. One-way analysis of variance was used to examine the relationships between categorical and continuous variables. To determine the usefulness of

the Kramer's scale as a screening test, we dichotomised the dermal zones 1 and 2 (head and neck and trunk) into one group the remaining 3 zones into the second group and calculated the sensitivity (how good the screening test is in detecting those who have the condition), specificity (how good the screening test is in detecting those who do not have the condition), positive predictive value (the probability of actually having the condition *given* that the screening test is positive), and the negative predictive value (the probability of not having the condition *given* that the screening test is negative). The reference standard was the total serum bilirubin level and we used the American Academy of Pediatrics guidelines to define the point at which phototherapy might be considered or recommended.[11] We calculated Statistical significance was defined as a *P*-value of < 0.05.

Results

A total of 405 otherwise healthy term newborns were enrolled in the study. The average age at which a TSB test was taken was 67 hours with a range of 5 to 243 hours. Statistically higher TSB levels were found in infants delivered by forceps compared with other modes of delivery (p = < 0.04). Cephalhaematoma was recorded for 16 (4%) infants (six spontaneous vaginal delivery, seven vacuum extraction, and three Caesarean section) and these infants were more likely to have a higher TSB levels than those infants who did not have a cephalhaematoma (p = < 0.03). Infants who had a caput succedaneum (n=10) also had higher TSB levels when compared with infants without a caput succedaneum (p = < 0.03). Eight of the 10 infants who developed caput succedaneum were delivered by vacuum extraction. There was a non-significant trend towards higher TSB levels among Asian infants but gender, feeding method or bruising had no effect on TSB levels (Table 1). A relationship was found between the dermal zones of the Kramer's scale and mean TSB levels (p = > 0.000) but confidence intervals were wide (Table 2). When the relationship between the Kramer's scale and TSB levels were controlled by age, phototherapy treatment was *justified* for 12 (3.3%) infants (Table 3) and a further 88 (24.2%) infants had TSB levels that warranted *consideration* for phototherapy (Table 4). When compared with the reference standard, the

Kramer's scale was inneffective as a screening instrument. At $\leq$ 48 hours the sensitivity was 67% and specificity was 48%. The positive and negative predictive values were 4% and 98% respectively. Between 49 and 72 hours the sensitivity was 89% and specificity was 54% with a positive predictive value of 10% and a negative predictive value of 99%. Of the 111 infants who had blood drawn for testing, who were over 72 hours of age, none required phototherapy.

Discussion

Our investigation was based on the well-known observation that jaundice associated with newborn infants generally appears first in the head and moves down the torso and finally to the soles of the feet and palms of the hands.[13] We also incorporated the notion, proposed by Kramer in 1969, that there was a relationship between this cephalocaudal progression and serum bilirubin levels.[13] Kramer found that bilirubin concentrations were correlated to 5 specific dermal zones although wide ranges of bilirubin levels were noted in each zone. Similar correlations have been found in other studies of both full term and preterm infants.[14-16] Our results are in line with these studies and we also found similar wide ranges in TSB levels in each of the dermal zones. These wide ranges explain why, even though there was a strong overall correlation between the level of jaundice and the 5 zones, the positive predictive value remained low.

Although our results were consistent with existing evidence, we were more interested in whether or not visual assessment, aided by use of the Kramer's scale, would assist with more precise targeting of infants who may require an intervention for jaundice, such as phototherapy. Our results do not support the use of Kramer's scale for this purpose. Age and TSB levels were recorded for 364 of the infants for whom a request for TSB levels had been made; only 12 required treatment with phototherapy. These results are not unusual. In one recent study only 3 of 164 infants who were assessed following hospital discharge were found to have TSB levels at which phototherapy would be *considered*.[17] Similarly, in a hospital-based cohort of 66 newborns who were assessed by nurses, just one was found to be within

treatment range.[18] Moyer and colleagues also concluded that decisions made by experienced practitioners about the need for serum bilirubin testing was not much better than would be predicted by chance.[19]

Unnecessary testing has considerable financial implications for health services. In our own facility the pathology service currently charges the hospital (Aus) $11.40 to collect and process blood for an estimate of TSB level. Considering that we order approximately 2,300 tests each year, costing in excess of (Aus) $26,000, there exists a potential for substantial cost savings.

The difficulty lies in understanding why so many needless tests are ordered and what can be done about it. Findings from earlier studies, which used cut-off points to assess TSB levels provide a useful guide. For example one author found that infants who were not jaundiced below the nipple line were unlikely to have bilirubin levels of 205 μmol/L[19] and another observed that none of the infants who were not visibly jaundiced below the knee had serum bilirubin levels greater than 188 μmol/L.[14] Apart from these results being somewhat contradictory, our larger study found that these levels were exceeded in every zone.

The current American Academy of Pediatrics clinical practice guideline[20] continues to recommend frequent assessment for jaundice by blanching the skin. The guideline also includes some parameters for decisions about laboratory investigation of jaundice after 24 hours. It suggests that blood should be taken if 'jaundice appears excessive for an infant's age' (p300) but this leaves practitioners again with subjective decision making. Our data indicate that significant hyperbilirubinaemia is present in very few infants and that more refined methods are needed for identifying those who are at greatest risk. A requirement for testing some infants is clear; for example where there is clinical jaundice less than 24 hours of age or a blood group incompatibility with a positive Coombs' test. Infants who sustain a

cephalhaematoma or caput succendaneum also need testing. For other infants transcutaneous bilirubinometry may be a practical and cost effective way of supplementing clinical observation; other studies suggest that there is a high correlation between bilirubin estimates from jaundice meters and TSB levels and that they perform well as a screening tool, to identify infants who may require TSB testing.[6,7,9]

Another approach would be to require that those who order tests are qualified to do so. Insisting on a demonstrated understanding of the current American Academy of Pediatrics guideline could form the basis for accreditation.

Conclusion

Our investigation has demonstrated the inadequacies of using the Kramer's scale to determine the need for TSB level testing. If the number of unnecessary tests is to be reduced, more accurate methods for identifying infants who may be at risk for hyperbilirubinaemia must be found.

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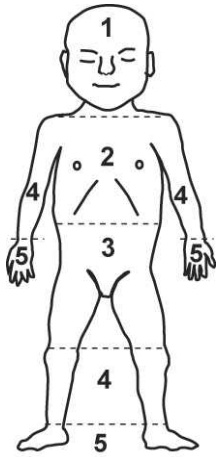

Figure 1 Dermal zones: 1) head and neck,
2) upper trunk, 3) lower trunk, thighs,
4) arms, legs below knee, 5) hands, feet.
(Kramer 1969,p 455).

Table 1 Demographic characteristics, risk factors and relationship to TSB levels

	N	TSB level Mean (SD)	95% Confidence interval	Sig
Gender				
Male	230	206.7 (54.4)	199.6 to 213.8	
Female	171	211.5 (56.6)	203.0 to 220.1	0.39
Type of Delivery				
Spontaneous vaginal delivery	201	210.8 (58.6)	202.7 to 218.9	
Forceps	14	241.6 (51.3)	212.0 to 271.2	
Ventouse Extraction	35	215.6 (64.8)	193.4 to 237.9	
Caesarean Section	146	201.0 (47.5)	193.2 to 208.8	< 0.04
Feeding Method				
Breast	291	211.8 (57.6)	205.2 to 218.5	
Formula	35	193.2 (46.9)	177.1 to 209.3	
Breast and formula	64	201.6 (47.6)	189.7 to 213.5	0.09
Ethnicity				
Caucasian	300	207.3 (53.7)	201.2 to 213.4	
Asian	50	220.9 (53.1)	205.8 to 235.9	
Other	43	196.1 (59.5)	177.8 to 214.4	0.17
Bruising				
Yes	53	213.6 (63.2)	196.2 to 231.1	
No	316	206.5 (52.5)	200.7 to 212.4	0.38
Cephalhaematoma				
Yes	15	239.2 (51.8)	210.5 to 267.9	
No	322	207.0 (52.9)	201.2 to 212.8	< 0.03
Caput succendaneum				
Yes	10	245.8 (57.5)	204.7 to 286.9	
No	320	206.8 (52.5)	201.0 to 212.6	< 0.03

* Spontaneous vaginal delivery

Table 2 Relationship between zones from Kramer's scale, and serum bilirubin levels

	N	Mean (SD)	Minimum	Maximum	95% Confidence Interval
Head and neck	54	183.39 (52.06)	74	318	169.18 to 197.60
Upper trunk	110	197.78 (47.31)	62	325	188.84 to 206.72
Lower trunk, thighs	87	220.77 (54.64)	107	340	209.12 to 232.42
Arms, legs below knees	79	226.30 (50.24)	96	329	215.05 to 237.56
Hands, feet	34	207.26 (55.41)	101	332	187.93 to 226.60
Total	364	207.31(54.48)	20	340	201.71 to 212.91

Table 3 Number of infants definitely requiring phototherapy according to the reference standard[11] using zones from Kramer's scale

Age (hrs)	Dermal zone when test ordered	Serum bilirubin level				Total
		< 260	260-310	311-340	> 340	
≤ 48	Head and neck	15	0	0	0	15
	Upper trunk	28	1	0	0	29
	Lower trunk, thighs	23	1	0	0	24
	Arms, legs below knees	18	1	0	0	19
	Hands, feet	7	0	0	0	7
Total		91	3*	0	0	94
49-72	Head and neck	17	2	0	0	19
	Upper trunk	48	5	1	0	54
	Lower trunk, thighs	26	3	6	0	35
	Arms, legs below knees	28	6	2	0	36
	Hands, feet	13	2	0	0	15
Total		132	18	9*	0	159
> 72 hrs	Head and neck	19	0	1	0	20
	Upper trunk	23	3	1	0	27
	Lower trunk, thighs	17	8	3	0	28
	Arms, legs below knees	13	10	1	0	24
	Hands, feet	8	3	1	0	12
Total		80	24	7	0	111

* Indicates number of infants where phototherapy is required

Table 4. Number of infants where phototherapy may be considered according to the reference standard[11] using zones from Kramer's scale

Age (hrs)	Dermal zone when test ordered	Serum bilirubin levels				Total
		≤ 170	171-260	261-290	> 290	
≤ 48	Head and neck	13	2	0		15
	Upper trunk	10	18	1		29
	Lower trunk, thighs	8	15	1		24
	Arms, legs below knees	4	14	1		19
	Hands, feet	1	6	0		7
	Total	36	55*	3*		94
49-72	Head and neck	8	9	1	1	19
	Upper trunk	16	32	4	2	54
	Lower trunk, thighs	4	22	3	6	35
	Arms, legs below knees	7	21	4	4	36
	Hands, feet	6	7	2	0	15
	Total	41	91	14*	13*	159
> 73	Head and neck	4	15	0	1	20
	Upper trunk	3	20	2	2	27
	Lower trunk, thighs	2	15	7	4	28
	Arms, legs below knees	1	12	7	4	24
	Hands, feet	1	7	1	3*	12
	Total	11	69	17	14	111

* Indicates number of infants where phototherapy may be considered